

TCT-342

Risk and Consequences of Periprocedural Myocardial Infarction Following Off-Label Use of Second Generation Drug-Eluting Stents: Two-Year Follow-up in the TWENTE Trial

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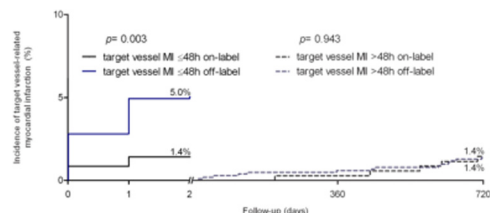
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Background: Drug-eluting stents (DES) were initially used 'on-label' in simple lesions and low-risk patients. Contemporary second-generation DES are more often used in 'off-label' settings, while there is limited knowledge about the potential increase in event risk.

Methods: We analyzed the 2-year clinical outcome data of 1387 TWENTE trial patients treated with liberal off-label use of second-generation everolimus-eluting Xience V or zotarolimus-eluting Resolute stents. Periprocedural myocardial infarction (PMI) was defined as myocardial infarction (MI) ≤ 48 hours following PCI. MI was defined as 2x the upper reference limit of creatine kinase (CK).

Results: Off-label patients (n=1033; 74.5%) had more diabetes (22.9% vs. 17.5%; $p<0.05$), previous MI (35.9% vs. 22.3%; $p<0.05$), complex lesions (76.1% vs. 60.7%; $p<0.05$), and acute coronary syndromes (57.8% vs. 33.3%; $p<0.05$). There was a higher incidence of periprocedural MI in off-label patients (5.0% vs. 1.4%; $p<0.05$), of whom merely 1.1% developed creatine kinase levels $>5\times$ ULN. Consequently, target vessel-related MI was higher in off-label patients (6.4% vs. 2.8%; $p<0.05$). Nevertheless, cardiac death and target vessel revascularization rates were similar for both groups ($p>0.8$).

Conclusions: Patients with off-label DES use had more periprocedural MI. Despite a higher risk profile and a higher rate of periprocedural MI, 2-year clinical outcome did not differ from that of patients with on-label DES use. Our findings underline the favorable safety profile of these second-generation DES in off-label settings.



presented in Figure 1. The NCDR model predicted post-PCI bleeding similarly in AA and non-AA (AUC 0.68 vs 0.72, $p=0.09$) (Figure 2), and the model's predictability was not enhanced by adding AA race as a variable using NRI analysis (NRI 4.8%, $p=0.20$).

Conclusions: The predicted post-PCI bleeding risk was higher in AA compared to non-AA; however, observed bleeding rates were similar. The NCDR bleeding risk score remained predictive of post-PCI bleed in both groups.

Figure 1: Frequency of bleeding across NCDR bleeding risk scores

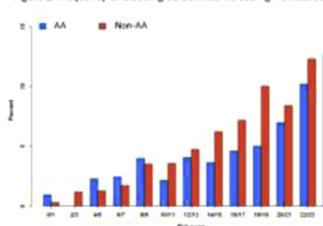


Figure 2: Logistic regression analysis comparing accuracy of NCDR risk score in predicting post-PCI bleed

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Contrast-induced nephropathy in patients undergoing primary percutaneous coronary intervention.

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Background: Contrast-induced nephropathy (CIN) is the third leading cause of acute renal failure in hospitalized patients and has a negative prognostic impact with increased mortality and hospital stay. The incidence of CIN in patients undergoing primary percutaneous coronary intervention (PCI) is higher than in programmed procedures. In primary PCIs, CIN prevention measures are less applied than in programmed PCIs. Aim: to analyze CIN in patients undergoing primary PCI and the role of hydration in its prevention.

Methods: 204 patients (62.8 \pm 13.8 years; 73.5% male) with STEMI who underwent primary PCI were randomly assigned to receive either hydration with normal saline: 1ml/kg/hour since the beginning of the procedure and 24 hours after it (SS group) or not (NS group). CIN was defined as a 25% or 0.5 mg/dL increase in serum creatinine \geq within 48-72 hours following the procedure.

Results: 41.2% had hypertension, 23.4% diabetes mellitus, 13.3% renal dysfunction and 15.9% anemia. Mean contrast volume used was 168 \pm 69 cc. There were no significant differences between the two groups regarding baseline features, apart from the higher contrast volume used in the SS group (180 vs 157 cc; $p=0.023$). 101 patients (49.5%) were included in SS group and 103 (50.5%) in NS group. We performed an intention to treat analysis with 26% of crossover between groups. CIN was observed in 17 patients (8.7%): 13 in the NS group and 4 in the SS group ($p=0.028$). Two of these patients needed extrarenal deapuration measures. The other predictors of CIN in the univariate analysis were the higher volume contrast used (217 vs 169 cc; $p=0.021$), the higher age (73.06 vs 62.01; $p=0.001$) and the lower hemoglobin prior the procedure (12.95 vs 14; $p=0.04$). In the multivariate analysis, the only predictors of CIN were the hydration (SS group): OR=0.19 (0.05-0.69), $p=0.012$ and the contrast volume used: OR=1.008 (1-1.015), $p=0.04$.

Conclusions: Even having received higher doses of contrast, the patients who received hydration during primary PCI (SS group), reduced by 53% the incidence of CIN. Given the higher incidence of CIN in emergent procedures, and the morbidity that it implies, we should improve prevention measures in these patients.

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Successful percutaneous retrieval of entrapped intravascular ultrasonography catheter.

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Background: Entrapment of an intravascular ultrasonography (IVUS) catheter is a rare but life-threatening complication of percutaneous coronary intervention (PCI). There is a paucity of data on frequency and treatment of entrapment of an IVUS catheter.

Methods: We retrospectively reviewed a total of 1852 consecutive patients (2096 lesions) who underwent PCI using 2351 stents (PtCr-EES, n = 1224, 52.1%; BES n = 749, 31.9%; CoCr-EES, n = 148, 6.3%; ZES, n = 92, 3.9%; SES, n = 9, 3.8%; PtCr-PES, n = 5, 0.2%; BMS, n = 124, 5.3%) in our hospital from June 2012 to May 2013. Of those, we use an IVUS catheter in 1610 patients (87.1%, 1802 lesions). IVUS catheter included View IT (Terumo, n = 1771, 98.3%), iLAB (Boston Scientific, n = 17, 0.9%), Volcano (Volcano, n = 8, 0.4%), and others (n = 5, 0.3%).

Results: During the study period, entrapment of an IVUS catheter at the stented lesion occurred in 10 lesions (0.6%, 13 stents). There was no significant difference in the stent (PtCr-EES n = 10, BES n = 3) and IVUS catheter (View IT n = 10). Of those,

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Does The National Cardiovascular Data Registry Bleeding Risk Score Accurately Predict Bleeding In African American Patients Undergoing Percutaneous Coronary Intervention?

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Background: The National Cardiovascular Data Registry (NCDR) bleeding risk score model was derived from a predominantly Caucasian population, with an under-represented African American (AA) population of 6%. Differential post-PCI bleeding rates have been reported. We aim to analyze the post-PCI bleeding rates in a better-represented AA population.

Methods: From our own PCI registry, bleeding (defined by NCDR CathPCI registry as transfusion, prolonged hospital stay and/or drop in hemoglobin $>3\text{g/dL}$) rates were compared between AA and non-AA patients. A logistic regression model was used to compare the accuracy of the NCDR risk score in predicting post-PCI bleed in AA and non-AA patients, and a net reclassification improvement (NRI) analysis was used to determine if the model's predictive ability was enhanced by adding AA race as a variable.

Results: A total of 22438 PCI patients were evaluated, of which 6396 (28.5%) were AA. Although NCDR bleeding risk score was higher in AA than in non-AA [median (IQR) 13 (8-18) vs 11 (6-17), $p<0.001$], overall observed bleeding event rates were similar (5.0% vs. 5.6%, $p=NS$). Observed bleeding event rates across risk scores are